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10/566,109	04/26/2006	Ian Douglas Makinson	1171/44327/163-PCT-US	9532
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CLARK HILL, PLC			STUART, COLIN W	
150 NORTH MICHIGAN AVENUE				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mkitz@clarkhill.com

Office Action Summary	Application No. 10/566,109	Applicant(s) MAKINSON ET AL.
	Examiner COLIN STUART	Art Unit 3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 08 April 2010.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-12 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-12 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 26 January 2006 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/GS-68)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

1. This office action is in response to the request for continued examination filed 4/8/10. As directed by the amendments filed with the request, claims 1 and 6 have been amended and no claims have been cancelled nor received. As such, claims 1-12 are pending in the instant application.

Claim Objections

2. Claim 3 is objected to because of the following informalities: It appears that the applicant has made a typographical error in line 1 which reads "humidifier is a eatable ...". It appears this should read --humidifier is a heatable ...--. Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kenyon et al. (6,397,841) in view of Koch (6,367,472) and Davies (6,516,798).

In regards to claim 1, Kenyon shows a humidified gases delivery apparatus which includes a housing 32, a pressurized gases supply 12 within the housing, a pressurized gases outlet 22 in the housing in fluid connection with the pressurized gases supply and adapted to make fluid connection with an inlet of a humidifier in order to provide pressurized gases flow to the humidifier 26 (see Fig. 1 and 3). Kenyon is silent as to providing a filter in the inlet of the humidifier and downstream of the pressurized gases supply, positioned such that the filter can filter pressurized gases entering the humidifier and protect the gases supply, humidifier and housing from contamination. However, Koch teaches a humidified gases delivery apparatus which includes a filter in the inlet of the humidifier positioned such that it can filter pressurized gases entering the humidifier and protect the pressurized gases supply, humidifier and housing from contamination (see Koch col. 1 ln. 53-56). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Kenyon device to include a filter at the inlet of the humidifier so that its positioned to filter pressurized air down stream of gases supply and protect from contamination as taught by Koch in order to ensure that "microorganisms cannot enter" (see Koch col. 1 ln. 55-56) the device. The now modified Kenyon reference is silent as to the filter explicitly

being removable. However, Davies teaches a humidification system which teaches removal and replacement of a filter as being a desired feature to prevent failure of the filter (see Davies col. 2 ln. 6-9). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Kenyon device so that the filter is removable as taught by Davies in order to replace an expired filter to avoid the airway becoming blocked by a dirty filter (see Davies col. 2 ln. 6-9).

In regards to claim 2, the modified Kenyon's device includes a humidified gases return in said housing, adapted to make fluid connection with an outlet of a said humidifier in order to receive humidified gases from said humidifier, (connection outlet 24; Kenyon et al. Fig. 1) and a patient outlet in said housing, in fluid connection with said humidified gases return in order to receive humidified gases from said humidified gases return and provide humidified gases to said patient outlet, said patient outlet being in fluid connection with or adapted to make fluid connection with a breathing conduit for delivery of humidified gases to a patient. (breathable gas outlet 14; Kenyon et al. Fig. 1).

5. Claims 3-4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kenyon et al. (6,397,841), Koch (6,367,472) and Davies (6,516,798) as applied to claim 1 or 2 above, and further in view of Mayer et al. (7,096,864).

In regards to claim 3, the modified Kenyon's device teaches all the limitations as discussed above, but is silent as to explicitly disclosing that the humidifier is a heatable water chamber with the limitations as claimed. However, Mayer teaches a device for

supplying respiratory gases which includes a humidifier as a heatable water chamber as claimed. (humidifying apparatus 2; Fig. 1 of Mayer et al.) Mayer et al. also teaches "introducing humidifying water into the liquid storage container 17" of the humidifying apparatus (col. 12 ln. 50; Fig. 1 of Mayer et al.) Mayer et al. also teaches that said apparatus includes, a chamber heating means connected to said housing as claimed. Mayer et al. discloses that the "water bath [of liquid in container 17] is preferably slightly heated by means of a heating device" (col. 3 ln. 58 Mayer). The humidifying apparatus including the heating means, when substituted for the humidifier of modified Kenyon et al., is connected to the housing as claimed. It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the humidifier of modified Kenyon et al. with the humidifying apparatus in view of Mayer et al., because Mayer et al. states that the humidifying apparatus is "coupled directly laterally to a CPAP-unit easily and without the need for expert assembly procedures" (col. 1 ln. 64 Mayer).

In regards to claim 4, the modified Kenyon's device includes an apparatus according to claim 3 wherein said humidification chamber has a base (base body 16; Fig. 1 of Mayer et al.). In regards to the claimed said chamber is engagable with said humidifier engagement via a single motion, and said single motion of engagement urges the base of said humidification chamber adjacent and in contact with said chamber heating means, connecting the substituted humidifying apparatus of Mayer et al. for the humidifier of Kenyon et al. would only require a single motion of connecting the tubes (24 & 25 Kenyon) with the humidifying apparatus. Connecting the substituted humidifying apparatus with the rest of the device of Kenyon et al. also makes a first fluid

connection between said pressurized gases outlet and said humidifier inlet, and makes a second fluid connection between said humidified gases return and said humidifier outlet, with said first and second fluid connections being made in the direction of said single motion as claimed.

6. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kenyon et al. (6,397,841), Koch (6,367,472) and Davies (6,516,798) as applied to claim 2 above, and further in view of Blackhurst et al. (WO 02/32486).

In regards to claim 5, the modified Kenyon device teaches all the limitations as discussed above, but is silent as to the patient outlet including a connector for receiving a breathing hose **and** at least one auxiliary electrical connection plug or socket or pneumatic connection plug or port, for a simultaneous connection with connecting a breathing circuit having complementary electrical and pneumatic connectors. However, Blackhurst teaches a breathing house with a connector (3 see Blackhurst Fig. 2) which also includes at least one auxiliary electrical connection plug or socket (Blackhurst Fig. 2 via connection 21 see also pg. 9 ln. 6-7) **or** pneumatic connection plug or port, for a simultaneous connection when connecting a breathing circuit having complementary electrical and pneumatic connectors (see Blackhurst Fig. 2; note that the breathing conduit and electrical connection are both connected simultaneously). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Kenyon device to include the auxiliary electrical connection plug as claimed as taught by Blackhurst in order to provide the ability to further heat the gas via

a breathing conduit heater element for example in order to maintain proper temperature and humidity level of the breathing gas being supplied to the patient.

7. Claims 6 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dickinson et al. (6,398,197) in view of Koch (6,367,472) and Davies (6,516,798).

In regards to claim 6, Dickinson shows a humidified gases delivery apparatus which includes a container 4 with a surrounding wall and top, and an open bottom (see Fig. 2 & 3), a heat conductive base 6 enclosing the open bottom of the container (see Fig. 3), a gases inlet 2 to the container for receiving pressurized gases for humidification from any pressurized gases supply, and an gases outlet 3 to the container (see Fig. 2 & 3). Dickinson is silent as to providing a filter in, on or over the inlet of the humidifier container and downstream of the pressurized gases supply, positioned to filter the gases entering the humidifier container. However, Koch teaches a humidified gases delivery apparatus which includes a filter in the inlet of the humidifier positioned such that it can filter pressurized gases entering the humidifier container (see Koch col. 1 ln. 53-56). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Dickinson device to include a filter at the inlet of the humidifier chamber so that its positioned to filter pressurized air downstream of gases supply taught by Koch in order to ensure that "microorganisms cannot enter" (see Koch col. 1 ln. 55-56) the device. The now modified Dickinson reference is silent as to the filter explicitly being removable. However, Davies teaches a humidification system

which teaches removal and replacement of a filter as being a desired feature to prevent failure of the filter (see Davies col. 2 ln. 6-9). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Dickinson device so that the filter is removable as taught by Davies in order to replace an expired filter to avoid the airway becoming blocked by a dirty filter (see Davies col. 2 ln. 6-9).

In regards to claim 12, the modified Dickinson's device includes a cylindrical chamber (see Fig. 2 Kenyon) but is silent as to explicitly disclosing that the inlet and outlet ports are **both** a female port (note only inlet 2 Dickinson clearly shows female port). However, one of ordinary skill in the art at the time the invention was made would have found it obvious to choose the ports to be a female connection port (as opposed to a male connection port) as this is considered to be a matter of design choice. Furthermore one would expect the modified Dickinson's device to perform equally as well with the claimed both female ports. Note that the ports open out to the cylindrical surface adjacent the top of the cylinder wall.

8. Claims 7 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dickinson et al. (6,398,197), Koch (6,367,472) and Davies (6,516,798) as applied to claim 6 above, and further in view of Hoffsrichter (DE 10,226,160) and Kenyon et al. (6,397,841).

In regards to claim 7, the modified Dickinson device teaches all the limitations as discussed above, including a first elongate flow tube extending into the humidifier

container from the inner periphery of the gases inlet (7 Fig. 2 of Dickinson). However, the modified Dickinson device is silent as to including a second elongate flow tube extending into said humidifier container from the inner periphery of said gases outlet. Hoffrichter teaches an air humidifier for a respirator which includes a tube extending into the humidification chamber from the inner periphery as claimed. (gauge-edge 18 of outlet pipe 9; Fig. 4 Hoffrichter) The two flow tubes taught by Hoffrichter are substantially parallel to each other, and substantially parallel to said base of said chamber. (See Fig. 4 Hoffrichter) It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the gases outlet of the modified Dickinson's device to include a parallel tube extending into the humidification chamber in view of Hoffrichter, because Hoffrichter states that this allows "the air current mixes with the steam without resistance, yet prevents water from flowing back" (Abstract Hoffrichter). The now modified Dickinson's device is silent as to having said gases inlet and said gases outlet facing the same direction, a preferred insertion direction, and said preferred insertion direction is substantially parallel to the said base of said chamber, such that said humidifier chamber may make operable engagement with a heater base in a single motion, and fluid connections with said gases outlet and said gases inlet, being also made in said single motion. Kenyon teaches a humidification apparatus where the gases inlet and outlet are facing the same direction and parallel to the base. (See Fig. 3 Kenyon) The inlet and outlet tubes are also parallel to the single motion engagement direction which make fluid connections during engagement. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the

modified device of Dickinson et al. to have the gases inlet and outlets configured in view of Kenyon, because Kenyon states that the engagement setup advantageously allows "the apparatus can be quickly and easily converted between including, or not including, a humidifier in the gas supply path" (col. 4 ln. 10).

In regards to claim 11, the modified Dickinson's device is silent as to the second flow tube including an air bleed orifice. However, Kenyon teaches a humidifier device which includes an air bleed orifice (64 Fig. 6 Kenyon) on a flow tube. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Dickinson's device's second flow tube to include an air bleed orifice as taught by Kenyon in order to provide a port in which sensors/transducers can monitor the activity of the device (see Kenyon col. 4 ln. 44-50).

9. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dickinson et al. (6,398,197), Koch (6,367,472) and Davies (6,516,798) as applied to claim 6 above, and further in view of Kurashima (6,033,455).

In regards to claims 8 and 10, the modified Dickinson device teaches all the limitations as discussed above, but is silent as to the filter including a framework substantially supporting a filter material and being shaped to fit an internal shape of the inlet and including a means to lock the filter in place in the inlet, the means to lock being friction fit. However, Kurashima teaches a filter which includes a framework (Kurashima 1 and 2 see Fig. 3 for example) supporting a filter material (Kurashima 15 see Fig. 3 for example) where the framework is shaped to fit the internal shape of the inlet via a

friction locking means (see Fig. 1 and 6 for example; note that inlet/outlets of the framework are sized to friction fit with a breathing conduit; see also Kurashima col. 6 ln. 38-41). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Dickinson device to include a filter with framework and friction locking as taught by Kurashima in order to provide structural support to the filter and to keep the filter from becoming dislodged.

In regards to claim 9, the modified Dickinson device's filter material (Kurashima 15) is disposed between the structural members of the frame work (see Fig. 1-6 of Kurashima).

Response to Arguments

10. Applicant's arguments with respect to claims 1-12 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following documents are considered to be pertinent art: Dobson et al. (5,564,415), Rose et al. (5,231,979), and Moberg (6,718,974).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to COLIN STUART whose telephone number is (571)270-7490. The examiner can normally be reached on M-F 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/COLIN STUART/
Examiner, Art Unit 3771

/Justine R Yu/
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